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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,577

12/27/2004

Joseph W. Villard

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT

PAPER NUMBER

3768

NOTIFICATION DATE

DELIVERY MODE

11/17/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@biopatentlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,577	<b>Applicant(s)</b> VILLARD ET AL.	
	<b>Examiner</b> HELENE BOR	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31, 57-63 and 65-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31, 57-63 and 65-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/15/2008 &amp; 12/27/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>journal articles</u> .                 |

## **DETAILED ACTION**

### ***Acknowledgement of Election/Restriction***

1. The Examiner acknowledges the election of Group I drawn to a blood substitute/hemoglobin with traverse. The Examiner notes that the Applicant cancelled Claims 32-56 without prejudice to their right to file divisional application directed to the subject matter of those claims.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite in regards to whether the language is a clear claim limitation.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 1-4, 7-9, 11-31, 75 & 79-82 are rejected under 35 U.S.C. 102(a) as being anticipated by Villard'2001.

Art Unit: 3768

**Claim 1-4, 7-9, 11-31, 75 & 79-82:** Villard teaches using Oxyglobin® [low-scattering, oxygen-carrying blood substitute] for OCT imaging of murine ventricle thickening (Page 25-28).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1-31, 57-63, 65-74, and 76 -78 are rejected under 35 U.S.C. 102(b) as being anticipated by Rameshraj et al. (Rameshraj Palaparthi, Huashan Wang, Anil Gulati, Current aspects in pharmacology of modified hemoglobins, Advanced Drug Delivery Reviews. Volume 40, Issue 3, Blood Substitutes, 28 February 2000, Pages 185-198).

**Claim 1:** Rameshraj teaches a method for performing treatment [wide variety conditions like trauma, elective surgery, oxygenation of tumors to make them more sensitive to radiation therapy, stroke etc.] of at least a first tissue in an animal, comprising providing into the blood associated with said at least a first tissue a biologically effective amount of a low scattering, oxygen-carrying blood substitute [Oxyglobin® having the inherent properties as disclosed in the Applicant's specification Page 24-25], and applying a treatment step [such as radiation therapy] to said at least a first tissue (Abstract, Page 185 Part I & Page 192 Part 2.6).

Art Unit: 3768

**Claim 2-4:** Rameshraj teaches a blood substitute which is substantially non-particulate, acellular, bovine hemoglobin solution [Oxyglobin®] (Page 187, Part 2 & Page 192, Part 2.6).

**Claim 5:** Rameshraj teaches a blood substitute which is human (Page 193, Part 2.7).

**Claim 6:** Rameshraj teaches a blood substitute which is recombinantly produced (Page 188, Part 2.2).

**Claim 7:** Rameshraj teaches a blood substitute which is crosslinked (Page 190, Part 2.4).

**Claim 8:** Rameshraj teaches a blood substitute which is polymerized (Page 190, Part 2.4).

**Claim 9:** Rameshraj teaches a blood substitute which is glutaraldehyde crosslinked polymerized (Page 193, Part 2.7).

**Claim 10:** Rameshraj teaches a blood substitute which is surface modified (Page 189, Part 2.3).

**Claim 11-21 & 31:** Rameshraj teaches using blood substitutes to replace whole blood or red blood cells [near-complete blood replacement study; 0.7%] (Page 192, Part 2.6).

**Claim 22-30:** Rameshraj teaches using a blood substitute [Oxyglobin®] with physical properties (Page 192, Part 2.6) that are inherent to the blood substitute as disclosed with the Applicant's Specification (Page 24-25).

**Claim 57-60 & 66-67:** Rameshraj teaches the tissue being brain (Page 187, Part 2.1).

**Claim 61-63:** Rameshraj teaches the tissue being cardiac (Page 192, Part 2.6).

Art Unit: 3768

**Claim 65 & 68-72:** Rameshraj teaches using animal for applying the treatment (Abstract, Page 185 Part I & Page 192 Part 2.6). It is inherent that an animal would be “at risk” to any number of disorders throughout its existence and certainly any animal would be at risk for a heart attack, cardiac valve defect, ischemic tissue, stroke and vascularized tumor (Page 190, Part 2.3).

**Claim 73-74:** Rameshraj teaches using an animal that is a mouse [rat/murine] or human (Page 188, Part 2.1 & Page 190, Part 2.4).

**Claim 76-78:** In implementing the blood substitute [Oxyglobin®] as disclosed above, one must obtain a Material Safety Data Sheet (BioPure MSDS; enclosed herein) as required by 20 CFR 1910.1200 Hazard Communication Standard to package the blood substitute with a MSDS as a kit. By OSHA regulation, MSDS sheet are available electronically online and available via hard copy within the work space the product is being used. Applicant is reminded that the details of the claimed “instructions” in a kit cannot serve to distinguish over a kit having the same elements and different printed “instructions”.

### ***Response to Arguments***

8. Applicant's arguments filed 03/28/2008 have been fully considered but they are not persuasive. The Applicant submitted the argument that the article, “Murine myocardium OCT imaging with a blood substitute”. Proc. SPIE Int. Soc. Opt. Eng. 4619, 165 (2002), submitted does not comply as evidence for Lack of Unity. The Examiner concedes that the original article was inappropriate in terms of the Date and two other references (Villard [Another Inventive Entity] and Rameshraj) are being applied that

Art Unit: 3768

show the technical feature of Claim 1 is not novel. The Lack of Unity is hereby maintained. The Examiner asserts that upon allowance of Claim 1 a rejoinder is possible with Group II.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. Ali AA, Ali GS, Steinke JM, Shepherd AP. Co-oximetry interference by hemoglobin-based blood substitutes. *Anesth Analg*. 2001;92:863–869.
- b. Segall; Paul E. et al. Blood substitute. US 4923442 A, 05/08/1990.
- c. Gould; Steven et al. Method for treating patients with massive blood loss. US 7291592 B2, 11/06/2007.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./  
Examiner, Art Unit 3768

/Eric F Winakur/  
Primary Examiner, Art Unit 3768